

APR - 9 1997

K964584

SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Product: OTOSILK™ Otological Graft Dressing

Description: The OTOSILK™ Graft Dressing is a sterile, disposable graft dressing constructed of non-adherent material, designed for use with split thickness skin grafts used in procedures such as tympanoplasty, canalplasty, mastoid tympanoplasty, correction of congenital aural atresia, and removal of canal exostoses.

Split thickness skin grafts may be taken from several sites, using either a razor blade or dermatome. The OTOSILK dressing will be used as a carrier for this skin graft to the ear canal. The graft is placed dermis side up on the dressing and the uncovered material is trimmed away. The skin graft and dressing are then applied to the canal. The dressing is removed from the canal one to two weeks post-operatively. The blue color of the OTOSILK Graft Dressing increases visualization of the dressing, ensuring total removal from the ear canal without disturbing the graft.

Indication For Use: To be used as a temporary dressing in the external auditory canal following tympanoplasty or stapedectomy procedures.

Predicate Device: Product No. XO-2904 originally marketed by Xomed (8641 Baypine Rd., Jacksonville, FL 32216) and subsequently marketed as Product No. 14-28010 by Xomed-Treace (6743 Southpoint Drive North, Jacksonville, FL 32216).

Testing: Sterile finished device samples passed biocompatibility testing and were determined to be non-reactive and non-cytotoxic.

Submitted by: _____
Stuart K. Montgomery, President

Date: _____